UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

PFIZER INC., PFIZER LIMITED and PFIZER IRELAND PHARMACEUTICALS, Plaintiffs and Counterclaim Defendants, v. TEVA PHARMACEUTICALS USA, INC., Defendant and Counterclaim Plaintiff.	Civil Action No. 2:10-cv-00128-RBS-FBS

TEVA'S MEMORANDUM IN SUPPORT OF ITS MOTION
FOR LEAVE TO FILE AN AMENDED ANSWER AND COUNTERCLAIM

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Defendant and Counterclaim Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") submits this memorandum in support of its November 12, 2010 Motion for Leave to File an Amended Answer and Counterclaim. Teva's motion seeks the Court's permission under Fed. R. Civ. P. 15(a)(2) to serve and file an amended pleading adding an affirmative defense and counterclaim that all of the claims of the patent-in-suit (U.S. Patent No. 6,469,012 ("the '012 patent")) are unenforceable because the applicants, including Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals (collectively, "Pfizer"), engaged in inequitable conduct during the prosecution of the application that led to the issuance of the '012 patent, and during the reexamination of the '012 patent in the United States Patent and Trademark Office ("PTO") from 2003 to November 2, 2010.

I. INTRODUCTION

Over the past three months during claim construction briefing, Teva has discovered facts and documents indicating that the applicants for the '012 patent, together with their attorneys and agents, and others associated with, or substantively involved in the prosecution of the application that led to the issuance of the '012 patent, engaged in inequitable conduct during the prosecution of that application by prosecuting and persuading the PTO to issue overbroad claims directed to the treatment of erectile dysfunction in a "male animal." Whitehill Decl. Ex. 1, '012 Patent, Claims 1–19 and 21–23.[1] Those facts demonstrate that the applicants and their attorneys and agents acted in bad faith, knowing that the claims directed to "animals" are overbroad and unpatentable. Those facts also show that the applicants and their counsel and agents withheld

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[1] "Whitehill Decl. Ex. __" refers to the corresponding Exhibit to the accompanying November 12, 2010 Declaration of Joshua A. Whitehill in Support of Teva's Memorandum in Support of Its Motion for Leave to File an Amended Answer and Counterclaim.

from the PTO highly material information about their knowledge of the overbreadth and unpatentability of those "animal" claims.

Teva's investigation over the past three months has also uncovered facts and documents showing that those individuals engaged in further inequitable conduct during the subsequent reexamination of the '012 patent by continuing to assert the validity of the "animal" claims in those proceedings from 2003 until November 2, 2010, even though Pfizer disclaimed nearly identical subject matter in a related counterpart Canadian patent on November 8, 2002, just 17 days after the '012 patent issued in the United States. Whitehill Decl. Ex. 2, '446 Patent at disclaimer no. 1.[2] Dr. Peter Ellis, one of the two inventors of the '012 patent at Pfizer, later explained in a 2005 declaration submitted to a court in Canada that Pfizer filed the Canadian patent disclaimer because the term "animal" in the claims was "much too broad in scope," "the wrong word to describe the scope of what was scientifically predictable," and "a mistake." Whitehill Decl. Ex. 3, Ellis Aff. at ¶¶ 59, 60. The applicants and their counsel concealed from the PTO in the United States the reasons why Pfizer Research and Development Company, N.V./S.A. filed the disclaimer in Canada by withholding and burying documents that discussed the substance of the Canadian disclaimer throughout the lengthy reexamination of the '012 patent.

Through their bad faith prosecution and acts of concealment, the applicants and their counsel persuaded the PTO to issue the overbroad claims of the '012 patent directed to animals (*i.e.*, claims 1–19 and 21–23), and prevented the PTO from noting and making it a matter of public record that those "animal" claims are overbroad and not patentable. As described more fully below and with particularity in Teva's proposed Amended Answer and Counterclaim, the

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[2] The disclaimer begins on the third page of the patent.

applicants for the ‘012 patent and their counsel breached their duties of candor and good faith to the PTO with deceptive intent to obtain broad claims to which they knew they were not entitled. That inequitable conduct renders each of the claims of the ‘012 patent unenforceable.

Teva respectfully submits that it should be permitted to serve and file its proposed Amended Answer and Counterclaims under Rule 15(a)(2) because it is seeking leave to do so without undue delay or bad faith, because Teva’s proposed inequitable conduct defense and counterclaim are not futile, because granting Teva leave to amend will not unduly prejudice Pfizer, and because justice will be served by allowing Teva to prove that the claims of the ‘012 patent should be held unenforceable as a consequence of Pfizer’s inequitable conduct.

II. BACKGROUND

A. Teva’s Allegations About Pfizer’s Inequitable Conduct

1. Inequitable Conduct During The Prosecution Of The ‘012 Patent

During the prosecution of the application for the ’012 patent, Dr. Peter Ellis and Pfizer Inc., through Pfizer, Inc.’s counsel, including at least James T. Jones, Esq., Gregg C. Benson, Esq., and Gerald M. O’Rourke, Esq. and perhaps others at Connolly, Bove, Lodge & Hutz (collectively, “Applicants”), sought and persuaded the PTO to allow claims directed broadly to treating erectile dysfunction in a male “animal,” in addition to claims directed more narrowly to treating erectile dysfunction in humans. The PTO issued the ‘012 patent on October 22, 2002 containing claims 1–19 and 21–23 directed to methods of treating erectile dysfunction in male animals (“animal claims”). Whitehill Decl. Ex. 1, ‘012 Patent, Claims 1–19 and 21–23. The Applicants knew before the ‘012 patent issued, however, that the animal claims were “much too broad in scope” and beyond “the scope of what was scientifically predictable.” Whitehill Decl. Ex. 3, Ellis Aff. at ¶ 59. On July 7, 1998, more than four years before the ‘012 patent issued in

the United States, Pfizer Research and Development Company, N.V./S.A. ("Pfizer R&D"), a Pfizer Inc. subsidiary, obtained a Canadian counterpart – Canadian Patent No. 2,163,446 ("the '446 patent") – from the Canadian Intellectual Property Office ("CIPO"). Whitehill Decl. Ex. 2, '446 Patent. The '446 patent and the '012 patent are counterparts because they share a common parent patent application (Whitehill Decl. Ex. 4, PCT '902), and they share a common patent specification (*compare* Whitehill Decl. Ex. 2, '446 Patent, *with* Ex. 1, '012 Patent). The Canadian '446 patent, like the U.S. '012 patent, issued with claims directed to treating erectile dysfunction in animals. Whitehill Decl. Ex. 2, '446 Patent, Claims 1–7, 10–13, 16, 17 and 20–24. On June 5, 2002, however, more than four months before the PTO issued the '012 patent in the United States, Bayer AG and Bayer Inc. (collectively, "Bayer") filed an action against Pfizer R&D in Canada alleging that the claims of the Canadian '446 patent were overbroad because the claimed subject matter directed to the treatment of erectile dysfunction in male animals was broader than the disclosure of the specification:

> As to claims 1 to 27, they … are broader than the alleged invention made by the named inventors and broader than the alleged invention described in the specification. There is no disclosure in the specification of any respect in which "the compounds of the invention" could be used for the curative or prophylactic treatment of erectile dysfunction in a male animal or sexual dysfunction in a female animal.

Whitehill Decl. Ex. 5, 06/05/02 Bayer Statement of Claim at ¶ 18(2).

Bayer's June 5, 2002 allegations prompted Pfizer R&D to file a document with the CIPO explicitly disclaiming all subject matter in the claims of the '446 patent that related to the treatment of erectile dysfunction or sexual dysfunction in non-human animals ("Canadian Disclaimer"). Whitehill Decl. Ex. 6, 11/14/02 Disclaimer Letter; s*ee also* Ex. 7, 12/05/02 Bayer Reply at ¶ 6. Pfizer R&D signed the Canadian Disclaimer on November 8, 2002, only a couple of weeks after the '012 patent issued in the United States. Whitehill Decl. Ex. 8, Canadian

Disclaimer at 5. Pfizer R&D's counsel at Bereskin & Parr filed the Canadian Disclaimer with the CIPO shortly thereafter on November 14, 2002. Whitehill Decl. Ex. 6, 11/14/02 Disclaimer Letter. One of Pfizer's two inventors, Dr. Ellis, testified in 2007 in a Canadian lawsuit involving the '446 patent that he consulted with attorneys at Bereskin & Parr about the subject of the Canadian Disclaimer before it was filed. Whitehill Decl. Ex. 9, 01/16/07 Ellis Depo. at 28:19–33:11.

In 2005, in another Canadian lawsuit involving the '446 patent, Counterclaim Defendant Pfizer Ireland Pharmaceuticals ("Pfizer Ireland")[3] submitted a sworn affidavit of Dr. Ellis ("Ellis Affidavit") in which he admitted that the Canadian Disclaimer was necessary because the claim term "animal" "was the wrong word to describe the scope of what was scientifically predictable," was "much too broad in scope," and that "[i]t was a mistake" that was "simply overlooked … at the time we filed the patent." Whitehill Decl. Ex. 3, Ellis Aff. at ¶¶ 59, 60. In particular, the Ellis Affidavit states:

> 59. On June 9, 1993, when we filed the original provisional application we included a paragraph on page 7 and 8 for use of the compound in a male animal for veterinary use and made the claims broad enough to include a male animal. We had not by that date done testing to show that an animal, other than [a] human suffering from erectile dysfunction, would benefit from the use of sildenafil or other cGMP PDE inhibitor. We did know, however, that many male animals have penises, which are similar in operation to that of a human, and it seemed reasonable from a scientific point of view to predict that this treatment would work in them as well as in men. ***The word "animal", however, was the wrong word to describe the scope of what was scientifically predictable.*** The term "Animal" includes a variety of living creatures such as mammals, birds, reptiles and insects. ***It is much too broad in scope. I simply overlooked this at the time we filed the patent. It was a mistake.***

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[3] Counterclaim Defendant Pfizer Ireland, a Pfizer Inc. subsidiary, is a successor-in-interest of the '446 patent. Whitehill Decl. Ex. 10, '446 Patent Assignments.

> 60. This mistake was corrected in the first disclaimer. All reference to animals was deleted from the claims.

Id. (emphasis added).

Documents produced by Pfizer in this action indicate that, in addition to Dr. Ellis, Pfizer Inc. and Pfizer Inc.'s United States patent counsel also knew about the overbreadth problem during the prosecution of the '012 patent. On June 12, 2002, Pfizer R&D's Canadian counsel at Smart & Biggar forwarded a copy of Bayer's June 5, 2002 overbreadth allegations in Canadian Case No. T-865-02 to Watson P. McMunn of Pfizer Limited's patent department. Whitehill Decl. Ex. 11, 06/12/02 Letter. Pfizer has produced a copy of the June 12, 2002 letter from counsel at Smart & Biggar to Mr. McMunn regarding Bayer's allegations which bears a handwritten notation "cc G O'Rourke." *Id*. That document indicates that Mr. O'Rourke was sent a copy of Bayer's allegations of overbreadth long before the issuance of the '012 patent.

The Applicants plainly appreciated the underlying "mistake" described in the Ellis Affidavit, *i.e.*, that just because an animal has a penis does not mean that it was "reasonable from a scientific point of view" to predict that the claimed erectile dysfunction treatment would work in non-human and human animals (Whitehill Decl. Ex. 3, Ellis Aff at ¶¶ 59, 60) – long before Bayer's June 5, 2002 allegations of overbreadth in its Canadian lawsuit against Pfizer. During the prosecution of the '012 patent, the Applicants repeatedly relied on a distinction between the anatomy of human and bovine penises to overcome an obviousness rejection based on a prior art scientific journal article that described tests conducted on bovine retractor penis tissue. Whitehill Decl. Ex. 12, Bowman 1984. In a February 10, 1998 communication to the PTO, for example, the Applicants stated: "First, it is noted that the retractor penis muscle has no role in penile erection in humans…. Thus, one looking for a cure for sexual dysfunction in humans would undoubtedly dismiss Bowman out of hand as irrelevant." Whitehill Decl. Ex. 13, 02/10/98

Response at 18; *see also* Ex. 14, Ballard Decl. at ¶ 7; Ex. 15, 08/05/98 Brief for Appellants at 18–19.

Documents obtained by Teva show that even though Dr. Ellis consulted with Pfizer R&D's counsel about the Canadian Disclaimer before it was filed (Whitehill Decl. Ex. 9, 01/16/07 Ellis Depo. at 28:19–33:11), and even though the Applicants appreciated and had argued during prosecution in the United States that treating erectile dysfunction in animals was not necessarily the same as treating erectile dysfunction in humans (Whitehill Decl. Ex. 13, 02/10/98 Response at 18), the Applicants continued to improperly prosecute overbroad animal claims until the PTO allowed those claims and the '012 patent issued (Whitehill Decl. Ex. 1, '012 Patent at Claims 1–19 and 21–23). The Applicants' bad faith prosecution of claims that they knew were overbroad and unpatentable was compounded by the Applicants' failure to disclose to the PTO that claims directed to treating erectile dysfunction in animals were "much too broad in scope," and failure to disclose Bayer's allegations of overbreadth to the PTO at any time before the issuance of the '012 patent. Any reasonable examiner at the PTO would have considered that information important in assessing the patentability of the animal claims, and therefore would have regarded that information as highly material. The Applicants, including at least Dr. Ellis and Messrs. Benson, Jones and O'Rourke, acted with deceptive intent to prevent the PTO from learning that those claims are overbroad for the purpose of securing claims broader than what the inventors believed they had invented.

2. Inequitable Conduct During Reexamination Of The '012 Patent

During the reexamination of the '012 patent, certain of the Applicants, including Dr. Ellis, as well as Pfizer Inc. and Pfizer Inc.'s counsel, including Gregg C. Benson, Esq. and James

T. Jones, Esq. (collectively, "Patentees"),[4] attempted to conceal from the PTO the overbreadth of the animal claims. The PTO reexamined claims 1–26 of the '012 patent from September 29, 2003 through May 10, 2010, and issued a reexamination certificate on November 2, 2010.[5] Whitehill Decl. Ex. 16, 09/29/03 Order for Reexamination; Ex. 17, 05/10/10 NIRC; Ex. 18, 11/02/10 Reexam Certificate.

Dr. Ellis plainly knew throughout the reexamination of the '012 patent that the animal claims of the '012 patent were "much too broad in scope" and therefore invalid. First, Dr. Ellis consulted with Pfizer R&D's counsel about the Canadian Disclaimer before it was filed in Canada, and before the reexamination of the '012 patent began. Whitehill Decl. Ex. 9, 01/16/07 Ellis Depo at 28:19–33:11. Second, on October 4, 2005, during the reexamination, Dr. Ellis signed the Ellis Affidavit, candidly admitting that the claim term "animal" was "much too broad in scope," "the wrong word to describe the scope of what was scientifically predictable," and "a mistake." Whitehill Decl. Ex. 3, Ellis Aff. at ¶¶ 59, 60. Although Dr. Ellis substantively participated in the '012 patent reexamination – he submitted two declarations to the PTO in 2005 (Whitehill Decl. Ex. 19, 03/29/05 Ellis Reexam Decl.; Ex. 20, 11/11/05 Ellis Reexam Decl.) – he did not at any time during the reexamination disclose to the PTO his knowledge that the animal claims were overbroad and invalid.

With respect to the Patentees, Pfizer Inc. and its counsel knew during the reexamination that the animal claims in the '012 patent were overbroad and invalid. For example, in 2007,

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[4] Teva reserves the right to later amend its inequitable conduct allegations to include any individuals that Teva learns through discovery substantively participated in the '012 patent prosecution or reexamination.

[5] When the PTO determines that a substantial new question of patentability has been raised with respect to claims of an issued patent, the PTO may reopen prosecution of that patent by ordering a reexamination proceeding. 35 U.S.C. §§ 303–05.

while the reexamination of the '012 patent was ongoing in the United States, Apotex Inc., one of Pfizer's competitors, specifically highlighted the discrepancy between Pfizer's Canadian patent claims and its United States patent claims in a Canadian lawsuit involving the '446 patent (Canadian Case No. T-1314-05). In its May 11, 2007 Memorandum of Fact and Law to the Canadian court, Apotex stated: "Although Pfizer alleges that the first disclaimer (December 2002) corrects various mistakes, ***it is curious that the corresponding U.S. patent, U.S. 6,469,012, which issued October 22, 2002, claims the treatment of ED in a male animal, the same "mistake" corrected in the '446 Patent***, which issued four years earlier. …" Whitehill Decl. Ex. 21, 05/11/07 Apotex Memorandum at ¶ 108 (emphasis added). In a later appeal in that action, Apotex filed an April 8, 2008 Memorandum of Fact and Law reiterating the observation about that discrepancy. Whitehill Decl. Ex. 22, 04/08/08 Apotex Memorandum at ¶ 104.

Notwithstanding Apotex's explicit references to the discrepancy between the claims of the Canadian and U.S. patents, the Patentees: (1) never affirmatively disclosed to the PTO that the animal claims of the '012 patent are overbroad; (2) never attempted to cancel the animal claims or otherwise disclaim subject matter in the '012 patent directed to treating erectile dysfunction in non-human animals; and (3) never disclosed Apotex's May 11, 2007 and April 8, 2008 Memoranda of Fact and Law (collectively, "Apotex Memoranda") to the PTO during the reexamination of the '012 patent.

The Patentees also deliberately buried the Ellis Affidavit among the thousands of references that the Patentees submitted to the PTO during the reexamination of the '012 patent. During the reexamination, the Patentees filed approximately 30 Information Disclosure Statements, listing more than 2,000 references. In the first five months of 2010 alone, the Patentees submitted at least nine Information Disclosure Statements, including more than 600

references containing more than 18,000 pages. Indeed, the PTO's recently issued reexamination certificate for the '012 patent contains 34 pages listing more than 2,000 references that were cited during the '012 patent reexamination. Whitehill Decl. Ex. 18, 11/02/10 Reexam Certificate at 1–34. On March 30, 2010, the Patentees finally submitted to the PTO an Information Disclosure Statement listing the Ellis Affidavit among 48 other references. Whitehill Decl. Ex. 23, 03/30/10 IDS at 3. The Patentees listed the Ellis Affidavit, however, only after (a) the Patentees had already dumped thousands of references on the PTO, (b) the Patentees had already submitted papers to PTO to cancel claim 24 of the '012 patent, which resolved the only issue remaining in contention in the '012 patent reexamination, (c) Pfizer had already filed the Complaint in this action, (d) four and a half years had passed since Pfizer Ireland filed the Ellis Affidavit in Canada, and (e) nearly seven and a half years had passed since Pfizer R&D filed the Canadian Disclaimer. *Id*. Furthermore, the Patentees' March 30, 2010 Information Disclosure Statement did not specifically draw attention to the Ellis Affidavit, or to Paragraphs 59 and 60 thereof concerning the Canadian Disclaimer, from among the dozens of other references disclosed that day, the hundreds of other references disclosed in 2010, or the thousands of references previously disclosed during the '012 patent reexamination. *Id*. at 1. Accordingly, the Patentees failed to put the PTO on notice that the Patentees knew that the claims covering treatment in animals were overbroad and invalid, and that the term "animal" is "much too broad in scope," "the wrong word to describe the scope of what was scientifically predictable," and "a mistake."

Through their acts of concealment, Dr. Ellis and the Patentees prevented the PTO from learning and making a public record that the animal claims in the '012 patent are overbroad. That overbreadth is highly material to the validity and patentability of the animal claims. The

foregoing acts of concealment demonstrate that Dr. Ellis and the Patentees, including at least Messrs. Benson and Jones, acted with deceptive intent to ensure that Pfizer would not have to surrender any part of its broad monopoly on using sildenafil citrate to treat erectile dysfunction in any animal, and to ensure that the inequitable conduct they committed during the '012 patent prosecution would remain hidden and undiscovered.

B. Teva's Discovery Of Facts Related To Its Inequitable Conduct Allegations

Rule 9(b) of the Federal Rules of Civil Procedure and controlling case law require Teva to plead its inequitable conduct defense and counterclaim with specificity. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009) (Rule 9(b) of the Federal Rules of Civil Procedure requires inequitable conduct pleadings to "identify the specific who, what, when, where, and how of the inequitable conduct."). Developing the factual who, what, when, where and how underpinnings of the inequitable conduct defense and counterclaim set forth in Teva's proposed Amended Answer and Counterclaim with the requisite degree of specificity required a massive undertaking. Before Teva could prepare its amended pleading, Teva had to acquire and review: (1) thousands of pages from the '012 patent prosecution history, including papers from the five '012 patent reexamination file histories; (2) thousands of pages from numerous lawsuits and opposition proceedings from around the world involving the '012 patent and foreign patents and patent applications related to the '012 patent; and (3) various other non-patent sources.

Teva first became aware of the discrepancy between Pfizer's Canadian patent claims and its United States patent claims in August 2010 while developing Teva's claim construction positions in this action. Specifically, while investigating how Pfizer and others involved in securing and enforcing patent rights in sildenafil had construed the claim term "a male animal in need of such treatment," Teva recognized for the first time that Dr. Ellis' statements in Paragraphs 59 and 60 of the Ellis Affidavit could have implications outside of Pfizer's patent

rights in Canada. During that investigation, Teva found that the Canadian Ellis Declaration, which primarily concerns Pfizer's research and development of sildenafil (the active ingredient in VIAGRA®), also explains why Pfizer R&D disclaimed certain subject matter in the Canadian '446 patent: "All reference to animals was deleted from the claims" of the '446 patent because the claim term "animal" was "much too broad in scope." In stark contrast, the '012 patent – asserted by Pfizer against Teva in this action – plainly includes numerous animal claims (*i.e.*, claims 1–19 and 21–23).

After it discovered Dr. Ellis' admissions, Teva investigated whether the animal claims of the '012 patent were procured through inequitable conduct. That investigation, which is ongoing, involved: (1) diligently exploring the facts and circumstances surrounding Pfizer's Canadian Disclaimer – including, for example, the scope of the Disclaimer, what prompted Pfizer to file the Disclaimer, and who was involved in preparing and filing the Disclaimer; (2) researching the various Canadian lawsuits involving the '446 patent and ordering relevant documents from Canadian courts; and (3) sorting through the voluminous disclosures and statements that the Applicants made to the PTO during the '012 patent prosecution and reexamination, to determine what, if anything, the Applicants did tell or disclose to the PTO about the scope of the claim term "animal," or their knowledge that the animal claims were overbroad.

Teva's investigation ultimately involved review of documents generated over the course of nearly twenty years by Pfizer, Pfizer's opponents, the PTO, foreign patent offices and United States and foreign courts. Nearly all of the documents that Teva relies upon to support the inequitable conduct defense and counterclaim set forth in Teva's proposed Amended Answer and Counterclaim were procured independently by Teva, rather than through discovery in this action,

which is just beginning. For example, the Apotex Memoranda (discussed above) were not disclosed to the PTO during the '012 patent prosecution or reexamination, and, to the best of Teva's knowledge, have not yet been produced by Pfizer in this action. Teva acquired those memoranda from Canada by its own means, and recognized that they are relevant to Teva's inequitable conduct defense only after meticulously analyzing many thousands of pages of documents over the past three months.

III. ARGUMENT

A. Legal Standards Governing Amendment Of Pleadings To Assert Inequitable Conduct

Rule 15(a)(2) of the Federal Rules of Civil Procedure sets forth a "permissive standard" for leave to amend pleadings, stating that leave "shall be freely given when justice so requires." *See Rambus, Inc. v. Infineon Technologies, AG*, 304 F. Supp. 2d 812, 819 (E.D. Va. 2004) (quoting Fed. R. Civ. P. 15); *see also Davis v. Va. Commonwealth Univ.*, 180 F.3d 626, 628 (4th Cir. 1999);[6] 3 JAMES WM. MOORE ET AL., MOORE'S FEDERAL PRACTICE § 15.14[1] (3d ed. 2010) ("The policy in favor of allowing amendments is extremely liberal."). "The law is well settled 'that leave to amend a pleading should be denied *only when* the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would be futile.'" *Edwards v. City of Goldsboro*, 178 F.3d 231, 242 (4th Cir. 1999) (quoting *Johnson v. Oroweat Foods Co.*, 785 F.2d 503, 509 (4th Cir. 1986)); *see also Atlantic Bulk Carrier Corp. v. Milan Exp. Co., Inc.*, No. 3:10cv103, 2010 WL 2929612, at *3 (E.D. Va. July 23, 2010). "Delay alone is an insufficient reason to deny leave to amend." *Edwards*, 178 F.3d at 242; *Atlantic Bulk Carrier*, 2010 WL 2929612, at *4. "Rather, the delay must be accompanied

by prejudice, bad faith, or futility." *Edwards*, 178 F.3d at 242; *Atlantic Bulk Carrier*, 2010 WL 2929612, at *4. In the Fourth Circuit, leave to amend under Rule 15(a) "should only be denied on grounds of futility when a proposed amendment is clearly insufficient or frivolous on its face." *MercExchange, L.L.C. v. eBay, Inc.*, 271 F. Supp. 2d 784, 788 (E.D. Va. 2002) (citing *Frank M. McDermott*, 898 F.3d 418, 423 (4th Cir. 1990) (concurring/dissenting opinion)); *see also Rambus*, 304 F. Supp. 2d at 823. At this stage in this action, Teva "do[es] not have to prove all the elements of [its] proposed count; it is sufficient that [Teva] demonstrate[s] that there is some plausible basis in the record for [its] claim." *Island Creek Coal Co.* v. *Lake Shore, Inc.*, 832 F.2d 274, 280 (4th Cir. 1987).

Claims of inequitable conduct must be pled with particularity in accordance with Rule 9(b). *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009); *see also Cent. Admixture Pharm. Servs. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356 (Fed. Cir. 2007); *Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1343-44 (Fed. Cir. 2003).[7] A pleading alleging inequitable conduct "must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen*, 575 F.3d at 1328; *see also Applied Interact, LLC v. Continental Airlines, Inc.*, No. 2:07cv341-HCM, 2008 WL 177740, at *5 (E.D. Va. Jan. 17, 2008) (pleadings must set forth "the time, place, and contents of the inequitable conduct, as well as the identity of the parties responsible for the inequitable conduct."). Knowledge and intent "may be averred

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[6] Fourth Circuit precedent is controlling regarding the issue of leave to amend pleadings under Rule 15(a), because it is a procedural matter not specific to patent law. *Rambus*, 304 F. Supp. 2d at 819 n.11.

[7] The precedent of the Court of Appeals for the Federal Circuit is controlling regarding the inequitable conduct analysis, because inequitable conduct involves questions of patent law. *Rambus*, 304 F. Supp. 2d at 819 n.11.

generally," so long as the pleading includes "sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Exergen*, 575 F.3d at 1328–29.

B. Teva's Motion For Leave To Amend Should Be Granted

In accordance with the express provision in Rule 15(a)(2) that "[t]he court should freely give leave when justice so requires," the Fourth Circuit has observed that a motion for leave to amend a pleading should be denied only when it would be prejudicial, there has been bad faith, or the amendment would be futile. *HCMF Corp. v. Allen*, 238 F.3d 273, 276-77 (4th Cir. 2001). None of those conditions is present here.

First, Teva's inequitable conduct defense and counterclaim are not futile. It is well established that a finding of inequitable conduct before the PTO may serve as a basis for holding a patent unenforceable. *Upjohn Co.* v. *Mova Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000). "Inequitable conduct requires a breach of the duty of candor that is both material and undertaken with intent to deceive the Patent and Trademark Office." *Frazier v. Roessel Cine Photo Tech Inc*., 417 F.3d 1230, 1234 (Fed. Cir. 2005). Such breaches include "[an] affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information." *Pharmacia Corp. v. Par Pharm. Inc*., 417 F.3d 1369, 1373 (Fed. Cir. 2005). The Court of Appeals for the Federal Circuit has ruled that materiality "embraces *any* information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent." *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001) (emphasis in original). Because "[d]irect evidence of intent or proof of deliberate scheming is rarely available in instances of inequitable

conduct" (*Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997)) intent may be, and often is, inferred from the surrounding circumstances (*see, e.g., Pharmacia Corp.*, 417 F.3d at 1373; *GFI*, 265 F.3d at 1274; *Ferring B.V. v. Barr Labs, Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006)).

Teva's proposed Amended Answer and Counterclaim sets forth, in the detail required under Rule 9(b), a meritorious inequitable conduct defense and claim that will render the '012 patent unenforceable. The proposed Amended Answer and Counterclaim provides a detailed account of the various breaches of the duties of candor and good faith, including the bad faith prosecution of the overbroad animal claims of the '012 patent, as well as Pfizer's withholding and burying of certain specific documents during the reexamination of the '012 patent over the past seven years. The proposed Amended Answer and Counterclaim also demonstrates that those breaches were material to the patentability of the animal claims in the '012 patent, and that Dr. Ellis, Pfizer Inc., and Pfizer Inc.'s counsel committed those breaches with intent to deceive the PTO. Teva's proposed Amended Answer and Counterclaim identifies the who, what, when, where and how of Pfizer's inequitable conduct and demonstrates that Teva's affirmative defense and counterclaim of inequitable conduct are not futile.

Second, Teva has not acted in bad faith or with undue delay. Inequitable conduct is a very serious allegation, and the courts encourage parties accused of patent infringement to investigate and confirm a claim of inequitable conduct before seeking to amend their pleadings. *See Douglas Press, Inc. v. Int'l Gamco, Inc.*, No. 00 C 7340, 2004 WL 2937392, at *1 (N.D. Ill. May 3, 2004) ("Because of the seriousness of this fraud like allegation, some district courts have allowed litigants to amend their pleadings to assert an inequitable conduct defense where new or corroborating evidence is discovered."); *see also Go Medical Indus. Pty. Ltd. v. C.R. Bard*, No.

1:93-cv-1538-HTW, 1995 WL 605802, at *4 (N.D. Ga. July 5, 1995) ("While defendant may have obtained some information to support its new allegations in September of 1994, this court will not penalize defendant for obtaining additional, confirming information in January 1995 to support its claims -- especially given that Rule 9(b) requires that allegations of fraud, such as inequitable conduct before the U.S. Patent Office, be stated with particularity.").

When Teva first learned of the discrepancy between Pfizer's Canadian claims and the claims of the '012 patent in the United States with respect to non-human animals, Teva undertook a massive, painstaking investigation to determine whether the facts demonstrate that Pfizer engaged in inequitable conduct during the prosecution and reexamination of the '012 patent. Teva has moved promptly to amend its Answer and Counterclaim after carefully determining that it could plead inequitable conduct with the degree of particularity required under Rule 9(b) and *Exergen*. Teva has acted in good faith and without undue delay to obtain, review and analyze documents from legal and patent office proceedings involving counterparts of the '012 patent around the world.

Third, allowing Teva leave to file its proposed Amended Answer and Counterclaim will not prejudice Pfizer. The information that forms the basis for Teva's inequitable conduct defense and counterclaim is known to Pfizer and is in Pfizer's possession. There is no need for Pfizer to engage in any discovery about this issue. Furthermore, Pfizer has easy access to the individuals alleged to have committed the inequitable conduct specified in Teva's proposed amended pleading.

Finally, this case is still in its early stages. Teva's proposed Amended Answer and Counterclaim will not necessitate the extension of any discovery, expert report or dispositive motion dates. Discovery is not scheduled to close for over four months, on March 7, 2011 for

Pfizer, and on April 4, 2011 for Teva. D.I. 37, at ¶ 3. The parties have agreed not to exchange responses to contention interrogatories until December 17, 2010. Neither party has taken any depositions yet. Granting Teva's motion would not require the Court to modify the discovery schedule or move the May 16, 2011 trial commencement date. D.I. 37, at ¶ 1.

Pfizer cannot establish any bad faith or undue delay on Teva's part, nor can it demonstrate that Teva's proposed Amended Answer and Counterclaim will result in any prejudice to Pfizer. *Atlantic Bulk Carrier*, 2010 WL 2929612, at *4 ("The party opposing amendment bears the burden of showing prejudice.").

IV. CONCLUSION

For all of the foregoing reasons, Teva respectfully asks the Court to grant Teva's Motion for Leave to File an Amended Answer and Counterclaim.

Dated: November 12, 2010

By: /s/

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CERTIFICATE OF SERVICE

I hereby certify that on the 12th day of November, 2010, I will electronically file the foregoing Teva's Memorandum in Support of Its Motion for Leave to File an Amended Answer and Counterclaim with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing to the following counsel of record:

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